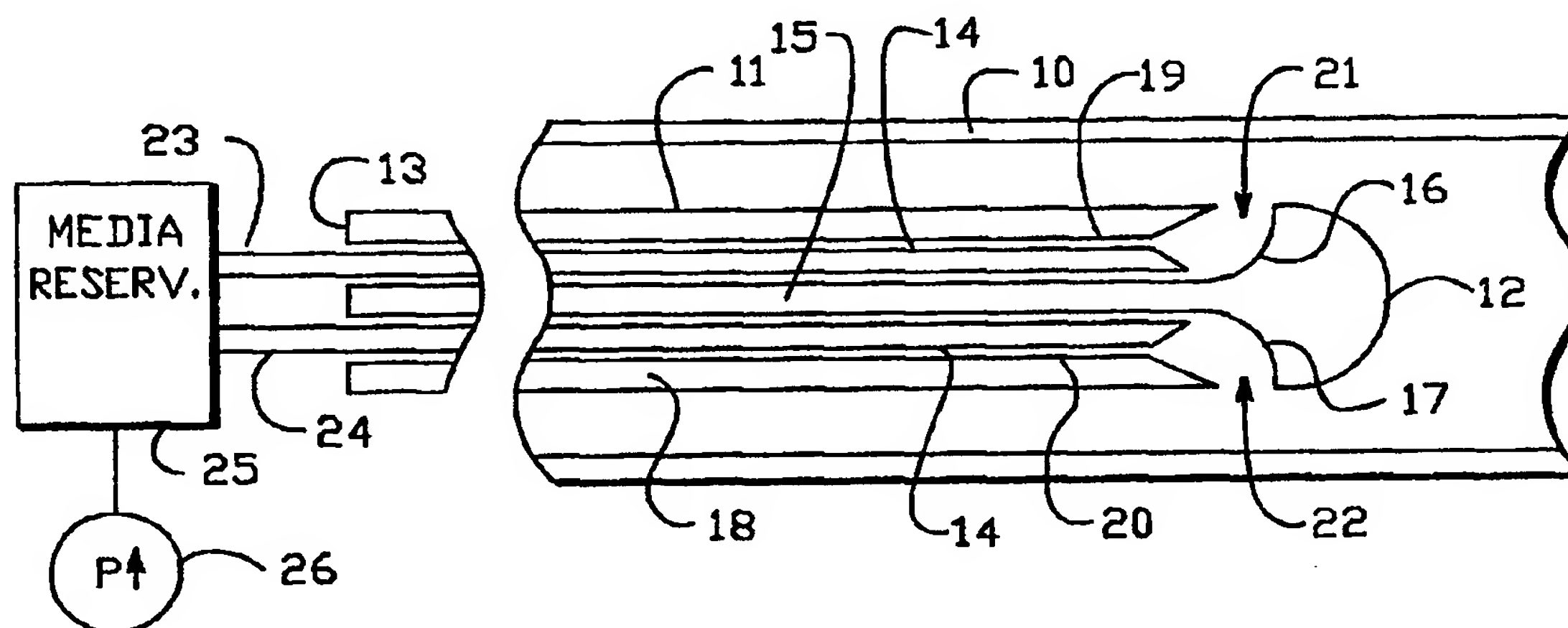




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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| (51) International Patent Classification ⁶ : A61M 5/145, 25/00 | A1 | (11) International Publication Number: WO 96/35464 (43) International Publication Date: 14 November 1996 (14.11.96) |
| (21) International Application Number: PCT/US96/06717 (22) International Filing Date: 10 May 1996 (10.05.96) (30) Priority Data: 08/440,368 12 May 1995 (12.05.95) US (71)(72) Applicant and Inventor: PERKINS, Rodney, C. [US/US]; 235 Mountain Wood Lane, Woodside, CA 94062 (US). (74) Agents: DAVIS, Paul et al.; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304 (US). | | (81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments. |

(54) Title: TRANSLUMENAL CIRCUMFERENTIAL INJECTOR



(57) Abstract

A tool for transluminal injection of material allows for more precise control over circumferential delivery of material adjacent the walls of a biological lumen or into a non-lumenous mass. The tool includes a catheter adapted to position within a biological lumen, including a plurality of guide channels extending to near the distal end of the catheter, each including a diverting region near the distal end which bends radially. Needles are placed within the guide channels such that they may slide in and out. The needle includes a relatively flexible portion near the distal end of the needle which, when forced against the diverting region of the guide channel, extends radially toward the circumference of the biological lumen. Thus, the needles may be positioned within the guide channels in a withdrawn position so that the distal ends of the needles lie within the guide channels, and in an extended position so that the distal ends of the needles are diverted by the diverting region of the guide channel and extend radially to the circumference of the lumen. A reservoir and pump mechanism is provided for supplying material through the needles. For the treatment of urinary incontinence, or other conditions based on the weakness of the wall of the biological lumen, the material injected may comprise collagen, or other insoluble fibrous proteins which provide structural support to the wall of the lumen.

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TRANSLUMENAL CIRCUMFERENTIAL INJECTOR

BACKGROUND OF THE INVENTION

Relationship to Copending Application

5 This application is a continuation-in-part of U.S. Patent Ser. No. 08,289,005, entitled Translumenal Circumferential Energy Delivery Device, filed August 11, 1994, which is incorporated herein by reference.

Field of the Invention

10 The present invention relates to medical devices, and more particularly to medical devices for delivering material to tissues of or surrounding biologic lumens such as the urethra, the esophagus, and blood vessels.

Description of the Related Art

15 A variety of medical conditions arise because of weakness of the walls of a biological lumen, such as the urethra, esophagus, or a blood vessel. One common condition, known as urinary incontinence arises as the sphincter and/or wall of the urethra becomes weakened.

20 Medical procedures have developed to treat urinary incontinence by the delivery of a material, such as collagen, to tissues surrounding the urethra in order to collapse the urethra, making it smaller, and to support the urethral wall. These techniques involve a difficult process of injecting material through the body to a position adjacent the urethra, requiring precise placement of the end of the delivery mechanism next to the wall of the urethra. Further, the procedure only delivers
25 material to one side of the lumen, causing an uneven delivery of pressure on the luminal wall. Also, the procedure is invasive, in that a needle is inserted through the skin of the body into the region of the urethra.

30 It is desirable to provide a technique for delivering material in a manner which more evenly surrounds the wall of the urethra, and which is less invasive. Also, such technology might be applied to treatment of a variety of other medical conditions based on the weakness of the walls of lumens, or to other conditions which might

benefit from circumferential delivery of material or removal of adjacent periluminal tissue to or through the luminal wall.

SUMMARY OF THE INVENTION

5 The present invention provides an apparatus for transluminal injection of material which allows for more precise control over the delivery of material adjacent the walls of a biological lumen. The apparatus comprises a catheter adapted to position within a biological lumen. At least one guide channel within the catheter extends to near the distal end of the catheter and includes a diverting region near the
10 distal end which bends radially. A needle is placed within the at least one guide channel such that it may slide in and out. The needle is relatively flexible, at least in a portion near the distal end of the needle, and when forced against the diverting region of the guide channel, extends radially toward the circumference of the biological lumen. Thus, the needle may be positioned within the guide channel in a withdrawn
15 position so that the distal end of the needle lies within the guide channel, and in an extended position so that the distal end of the needle is diverted by the diverting region of the guide channel and extends radially. A reservoir and pump mechanism, or an adaptor for connection to the same, is provided for supplying material through the needle.

20 In one aspect of the invention, the material delivered by the apparatus is relatively viscous, and the source of pressure coupled to the reservoir is adapted to drive the viscous material through the needle of the catheter.

 For the treatment of urinary incontinence, or other conditions based on the weakness of the wall of the biological lumen, the material may comprise collagen, or
25 other insoluble fibrous proteins which provide structural support to the wall of the lumen. Other viscous biocompatible structural materials, including but not limited to Teflon, are suitable.

 The catheter may be adapted, by way of example, as a transurethral probe, a probe adapted for transluminal positioning in an esophagus, or a probe adapted for
30 transluminal positioning in a blood vessel.

 A preferred embodiment of the present invention includes multiple guide channels and multiple needles. Preferably, there are three to six or more guide

channels arranged in a radially symmetric pattern. Material is forced through the needles simultaneously by the reservoir/pump mechanism. Thus, for the transurethral embodiment, the plurality of needles extends circumferentially through a urethral wall in the extended position to inject material into tissue outside the urethral wall.

5 Although the embodiments described above are directed to the delivery of structural material, such as collagen, to the region outside the walls of the biological lumen, the mechanism may be used as well for delivery of other types of material, including medicines and the like, to or through the wall of the biological lumen.

10 Thus, the present invention provides an apparatus for non-invasive delivery of material circumferentially to or through a luminal wall, which provides good control over the distribution of the material delivered relative to the circumference of the lumen.

 Other aspects and advantages of the present invention can be seen upon review of the figures, the detailed description, and the claims which follow.

BRIEF DESCRIPTION OF THE FIGURES

15 Fig. 1 is a schematic cross-sectional view of a transluminal injection probe according to the present invention, with needles in the withdrawn position.

20 Fig. 2 is a schematic cross-sectional view of the transluminal injection probe of the present invention with the needles in an extended position.

 Fig. 3 is a schematic end view of the transluminal probe illustrating a radially symmetric implementation.

 Fig. 4 illustrates schematically the effect of delivery of a structural material outside the wall of a biological lumen using the probe of Fig. 3.

25 Fig. 5 is a schematic end view of a transluminal probe with a single circumferential injector according to the present invention.

 Fig. 6 is a schematic illustration of the effect of delivery of material using the probe of Fig. 5.

30 Fig. 7 is a schematic illustration of an adaptor and the source of material and pressure for driving a media through the needles of the probe of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A detailed description of the present invention is provided with respect to Figs. 1-7, in which Figs. 1 and 2 illustrate the basic mechanism of the present invention. Figs. 3-6 illustrate the circumferential delivery of material using alternative
5 embodiments of the probe of Figs. 1 and 2. Fig. 7 illustrates a mechanism for pumping material through the needles of the probe.

Fig. 1 is a schematic view of an apparatus for delivering materials circumferentially in a biological lumen according to the present invention. Shown in the figure is a cross-sectional view of a biological lumen 10 with probe 11 inserted
10 therein. The probe 11 extends from a proximal end 13 to a distal end 12. Within the probe 11 are a plurality of guide channels (e.g., 14). Within probe 11, a light and/or viewing channel 15 is provided which can be an endoscope with light transmission and imaging lenses arranged therein. This permits the operator to visualize the
15 localization zone of the particular tissue being treated in which probe 11 lies. The guide channels have a diverting region, generally 16 and 17, which bends radially toward the circumference of the lumen 10. The probe 11, according to one
embodiment of the present invention, consists of a steel outer tube 18 with a closed end 19 near the distal end 12 of the probe 11. Within the outer tube 18 are a plurality of guide tubes (e.g., 19, 20) for the respective guide channels 14, 15. The tubes 19, 20
20 extend to and are bonded to the outer tube 18 near the distal end 12, such that the tubes 19, 20 have openings, generally 21, 22.

Flexible, hollow needles 23, 24 extend from the proximal end 13 of the probe to near the distal end 12 of the probe 11. The needles have at least a flexible portion near the distal end such that when extended through the openings 21, 22, the needles
25 bend radially toward the circumference of the lumen 10.

The needles 23, 24 are coupled with an adaptor (not shown) to a media reservoir 25. A pump 26 is coupled to the media reservoir 25 for simultaneously delivering material through the needles 23, 24.

Fig. 1 illustrates the needles 23, 24 in a withdrawn position, such that the
30 needles do not extend out openings 21, 22. The probe 11 is positioned within the lumen 10 using techniques known in the art. For instance, for a transurethral probe, a sheath with an obturator may be positioned within the urethra. The obturator is

removed, and the probe 11 is inserted through the sheath in place of the obturator. Rectal ultrasound, or other monitoring techniques, may be used to precisely position the distal end 12 of the probe 11 within the urethra prior to extending the needles, and delivering the material. Additionally, the position of extended needles 23, 24 can be
5 monitored by rectal ultrasound in other applications, including but not limited to the destruction of tissue.

Fig. 2 illustrates the probe of Fig. 1, with the needles 23, 24 in an extended position. The reference numbers in Fig. 2 are the same as the reference numbers in Fig. 1 for like elements. After the distal end 12 of the probe 11 is positioned within
10 the lumen 10, the needles 23 and 24 are driven longitudinally in the direction of the distal end 22, as schematically illustrated in Fig. 2 by the position of the media reservoir 25, relative to the position of the same in Fig. 1. By forcing the needles 23, 24 to the extended positions, the diverting region 16, 17 of the guide channels 14, 15 deflect the needle ends 30, 31 toward the circumference of the lumen 10. As
15 illustrated in Fig. 2, the needles may be extended radially through the wall of the lumen 10 to deliver material outside the wall 10. Thus, it can be seen that the needles 23, 24 have a withdrawn position (Fig. 1), in which the tips 30 and 31 are within the guide channels, and an extended position (Fig. 2) in which the tips 30 and 31 extend to or through the wall of the lumen 10.

20 The probe according to Figs. 1 and 2 may be manufactured using a variety of materials, including steel. For instance, the probe 11 may be manufactured using a flexible plastic material, adapted for use in smaller vessels.

The needles 23, 24 used in the system according to the present invention may be manufactured using steel tubing, or plastic tubing, or a combination thereof as suits
25 the needs of a particular treatment. The ends 30, 31 of the needles may include hard caps to aid penetration of a particular tissue being treated. The hard cap would then be coupled with a more flexible tubing which would react appropriately to the diverting regions 16, 17 of the guide channel.

Fig. 3 provides an end view of the probe 11 within lumen 10. In Fig. 3, the
30 probe is equipped with six needles 50, 51, 52, 53, 54, and 55. The six needles 50-55 are arranged in a radially symmetric pattern about the probe 11, and extend through the wall of the lumen 10 to deliver material generally represented by clouds 60, 61,

62, 63, 64, and 65. Viewing channeling 15, with associated light transmission and imaging lenses arranged therein, permit the operator to visualize the delivery of the material.

5 After delivery of the material using the probe 11, the probe is withdrawn, as illustrated in Fig. 4. The presence of the material represented by clouds 60-65 outside the wall of the lumen 10, and the pressure of the surrounding tissue tends to close the lumen in a substantially radially symmetric manner as shown in Fig. 4. By delivering greater amounts of material, the lumen may be completely closed. Also, if the material is a viscous biocompatible structural material, such as collagen or Teflon,
10 the walls of the lumen 10 are supported by the circumferential delivery provided by the probe according to the present invention. Furthermore, the wall of the lumen is relatively unharmed by the injection and will normally heal completely.

Fig. 5 illustrates an end view of a probe 70 according to the present invention inserted within lumens 71. Probe 70 has a single needle 72 which is diverted radially
15 through the circumference of the lumen 71. Using the probe 70, material 73 is delivered outside the wall of the lumen 71. When the probe 70 is withdrawn, the material 73, under pressure of the surrounding tissue, causes the lumen 71 to close. Also, the material 73 supports the wall of the lumen 71 in the region of the material. After delivery of the material 73, the surgeon may rotate the probe 70 to deliver the
20 material 73 in any desired pattern surrounding the wall of the lumen 71.

The single needle embodiment of Fig. 5 may be preferable for very small diameter lumens. However, this system suffers the disadvantage that the surgeon is responsible for even distribution of the material 73 around the circumference of the lumen 71. However, even asymmetric deposition is useful in certain applications.

25 Fig. 7 provides a simplified schematic diagram of an adaptor mechanism for connecting the needles in probe 80 to a source of material to be injected according to the present invention. In Fig. 7, the proximal end of probe 80 is illustrated. Needles 81, 82, and 83 extend out of the proximal end of the probe 80, and as appreciated with reference to Figs. 1 and 2, through guide channels down the length of the probe 80.
30 The probe 80 is secured to a sheath 84. The sheath 84 is connected with plate 85. Needles 81, 82, and 83 terminate with connectors 86, 87, 88 in plate 85. The connectors 86, 87, and 88 are coupled to respective tubes 89, 90, 91. The flexible

tubes 89, 90, and 91 are coupled to connectors 92, 93, 94 on a media reservoir 95. The connectors 92, 93, 94 extend into the media reservoir to receive material to be delivered using the probe 80. Coupled with the media reservoir 95 is a pump 96 for applying pressure to material within the media reservoir 95 such that it flows through tubes 89, 90, and 91 into the needles 81, 82, and 83.

The media reservoir 95 and pump 96 in Fig. 7 are schematically illustrated. It will be appreciated that this mechanism may be adapted to provide a metered volume of material through the needles 81, 82, and 83 in response to pressure from the pump 96.

The media reservoir in pump 96 may be manually operated, like a syringe, or motor driven. If the material to be delivered within the media reservoir 95 is relatively viscous, such as collagen, a significant pressure may be required to drive the material down the length of the narrow needles.

In operation, the probe 80 is placed within the lumen subject of treatment. The plate 85 is then driven toward the probe 80, with alignment and protection of the structure of the needles 81, 82, and 83 provided by the sheath 84. The flexible tubing 89, 90, 91 allows for the range of motion of the plate 85 required for withdrawing or extending the needles through the probe 80. Also, the plate 85 may provide a stop mechanism, which prevents over-extension of the needles out of the probe 80.

Thus, according to the present invention, a material may be delivered circumferentially to biological lumens, such as the urethra, esophagus, or blood vessels, to support the wall of the lumens, or to collapse the lumen as needed for treatment of a particular condition. Thus, in a preferred system, the material delivered using the probe according to the present invention comprises collagen, or other insoluble fibrous protein that may provide a structural support to the wall of the lumen. However, the present invention may be adapted to deliver a variety of liquid or viscous materials circumferentially in biological lumens as suits the needs of a particular procedure.

A simplified mechanism for circumferential delivery of material to a biological lumen using a transluminal probe has been provided. The transluminal probe is relatively non-invasive and simple to use compared to prior art systems for delivering material used in treatment adjacent to or on the walls of biological lumens.

Probe 80 can also be used in non-lumenous tissues such as solid masses. With a solid mass an instrument such as a trocar can be used to penetrate the solid mass. The trocar is then removed, probe 80 introduced, and the needles can then distribute a variety of different foci of material throughout the mass, including but not limited to cancer fighting materials, radiation pellets, collagen and the like. When probe 80 is introduced into a solid mass, tissue destruction within the mass is achieved by the delivery of energy or foci of material which destroy tissue such as cancer fighting agents.

The foregoing description of preferred embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention for various embodiments and with various modifications as are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims and their equivalents.

CLAIMS

What is claimed is:

- 5 1. An apparatus for transluminal injection of material, comprising:
 a catheter having a proximal end and a distal end to position within a
 biological lumen;
 at least one guide channel within the catheter extending from near the
 proximal end to near the distal end of the catheter, and including a diverting region
10 near the distal end bending radially;
 a needle within the at least one guide channel having a distal end, and a
 relatively flexible portion near the distal end of the needle, wherein the needle within
 the at least one guide channel may be positioned in a withdrawn position so that the
 distal end of the needle lies within the guide channel, and in an extended position so
15 that the distal end of the needle is diverted by the diverting region of the guide
 channel and extends circumferentially; and
 an adaptor, coupled with the needle, to supply material into the needle.
- 20 2. The apparatus of claim 1, further including:
 a reservoir of material coupled to the adaptor; and
 a source of pressure coupled to the reservoir to force material through the
 needle.
- 25 3. The apparatus of claim 1, wherein the biological lumen has a wall, and
 the needle extends through the wall in the extended position.
- 30 4. The apparatus of claim 1, further including:
 a reservoir of relatively viscous material coupled to the adaptor; and
 a source of pressure coupled to the reservoir to force the relatively viscous
 material through the needle.

5. The apparatus of claim 1, wherein the material comprises a viscous biocompatible material.

6. The apparatus of claim 1, wherein the material comprises collagen.

5

7. The apparatus of claim 1, wherein the catheter comprises of a transurethral probe.

10

8. The apparatus of claim 1, wherein the catheter comprises an endoscope.

9. The apparatus of claim 1, wherein the catheter comprises a probe adapted for transluminal positioning in an esophagus.

15

10. The apparatus of claim 1, wherein the catheter comprises a probe adapted for transluminal positioning in a blood vessel.

20

11. An apparatus for transluminal injection of material, comprising:
a catheter having a proximal end and a distal end to position within a biological lumen;

a plurality of guide channels within the catheter extending from near the proximal end to near the distal end of the catheter, each guide channel including a diverting region near the distal end bending radially;

25

a plurality of needles within corresponding guide channels in the plurality of guide channels having distal ends, and relatively flexible portions near the distal ends, wherein the plurality of needles within the plurality of guide channels may be positioned in a withdrawn position so that the distal ends of the plurality of needles lie within the guide channels, and in an extended position so that the distal ends of the plurality of needles are diverted by the diverting regions of the guide channels and extend circumferentially; and

30

an adaptor, coupled with the plurality of needles, to supply material into the plurality of needles.

12. The apparatus of claim 11, wherein the plurality of needles included at least three needles.

5 13. The apparatus of claim 12, wherein the diverting regions of the plurality of guide channels establish a substantially radially symmetrical pattern.

14. The apparatus of claim 11, further including:
a reservoir of material coupled to the adaptor; and
a source of pressure coupled to the reservoir to force material simultaneously
10 through the plurality of needles.

15 15. The apparatus of claim 11, wherein the biological lumen has a wall, and the plurality of needles extend circumferentially through the wall in the extended position.

16. The apparatus of claim 11, further including:
a reservoir of relatively viscous material coupled to the adaptor; and
a source of pressure coupled to the reservoir to force the relatively viscous
material simultaneously through the plurality of needles.

20 17. The apparatus of claim 11, wherein the material comprises collagen.

18. The apparatus of claim 11, wherein the catheter comprises of a transurethral probe.

25 19. The apparatus of claim 18, wherein the material comprises collagen, and the plurality of needles extend circumferentially through a urethral wall in the extended position to inject the material into tissue outside the urethral wall.

30 20. The apparatus of claim 11, wherein the catheter comprises a probe adapted for transluminal positioning in an esophagus.

21. The apparatus of claim 11, wherein the catheter comprises a probe adapted for transluminal positioning in a blood vessel.

22. An apparatus for transluminal injection of material, comprising:

5 a catheter having a proximal end and a distal end to translumenally position within a biological lumen and having a circumference near the distal end;

a plurality of guide channels within the catheter extending from near the proximal end to near the distal end of the catheter, each guide channel including a diverting region near the distal end bending radially in a direction toward the circumference of the catheter near the distal end, the diverting regions of the plurality of guide channels formed in a substantially radially symmetrical pattern;

10 a plurality of needles within corresponding guide channels in the plurality of guide channels having proximal ends and distal ends, and relatively flexible portions near the distal ends, wherein the plurality of needles within the plurality of guide channels may be positioned in a withdrawn position so that the distal ends of the plurality of needles lie within the guide channels, and in an extended position so that the distal ends of the plurality of needles are diverted by the diverting regions of the guide channels and extend circumferentially;

a reservoir of material coupled to the plurality of needles; and

20 a source of pressure coupled to the reservoir to force material simultaneously through the plurality of needles.

23. The apparatus of claim 22, wherein the biological lumen has a wall, and the plurality of needles extend circumferentially through the wall in the extended position to inject the material in a substantially radially symmetric pattern outside the wall of biological lumen.

24. The apparatus of claim 22, wherein the material comprises relatively viscous material.

25. The apparatus of claim 22, wherein the material comprises collagen.

26. The apparatus of claim 22, wherein the catheter comprises of a transurethral probe.

27. The apparatus of claim 22, wherein the material comprises collagen, and the plurality of needles extend circumferentially through a urethral wall in the extended position to inject the material in a substantially radially symmetric pattern into tissue outside the urethral wall.

28. The apparatus of claim 22, wherein the catheter comprises a probe adapted for transluminal positioning in an esophagus.

29. The apparatus of claim 22, wherein the catheter comprises a probe adapted for transluminal positioning in a blood vessel.

30. An apparatus for injection of material into a non-lumenous mass comprising;

a catheter having a proximal end and a distal end to position within the non-lumenous mass;

at least one guide channel within the catheter extending from near the proximal end to near the distal end of the catheter, and including a diverting region near the distal end bending radially;

a needle within the at least one guide channel having a distal end, and a relatively flexible portion near the distal end of the needle, wherein the needle within the at least one guide channel may be positioned in a withdrawn position so that the distal end of the needle lies within the guide channel, and in an extended position so that the distal end of the needle is diverted by the diverting region of the guide channel and extends circumferentially; and

an adaptor, coupled with the needle, to supply material into the needle.

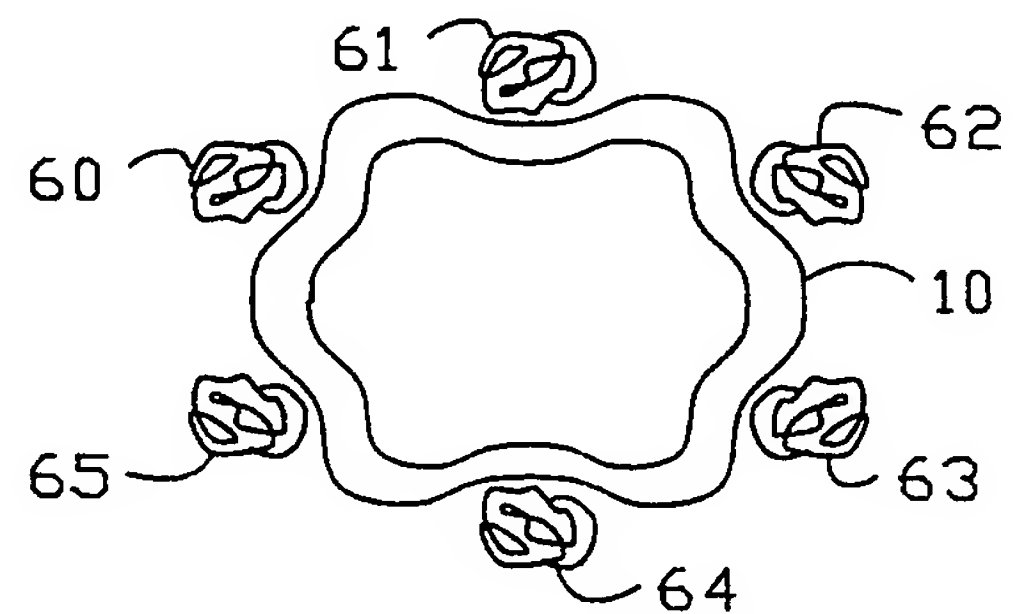
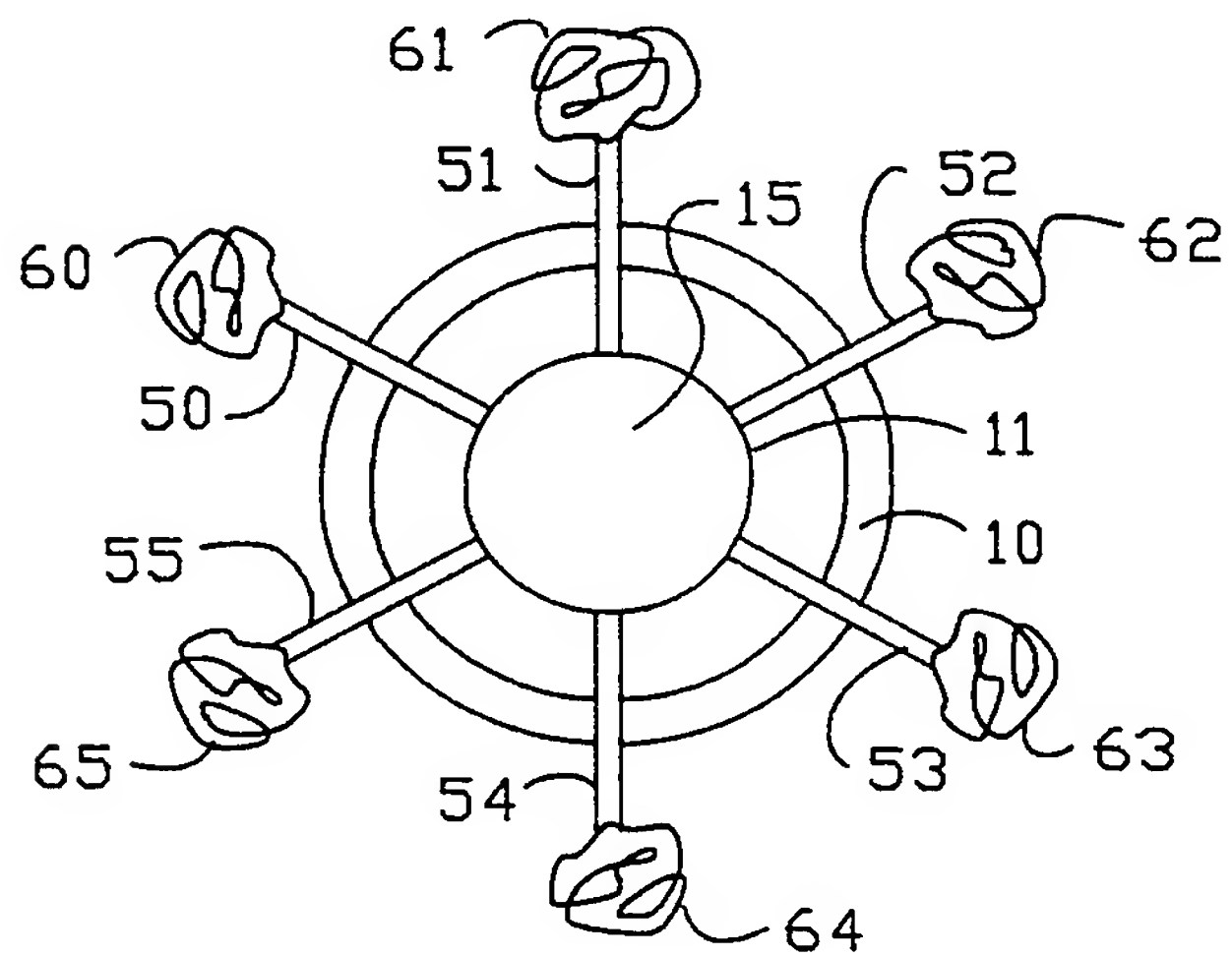
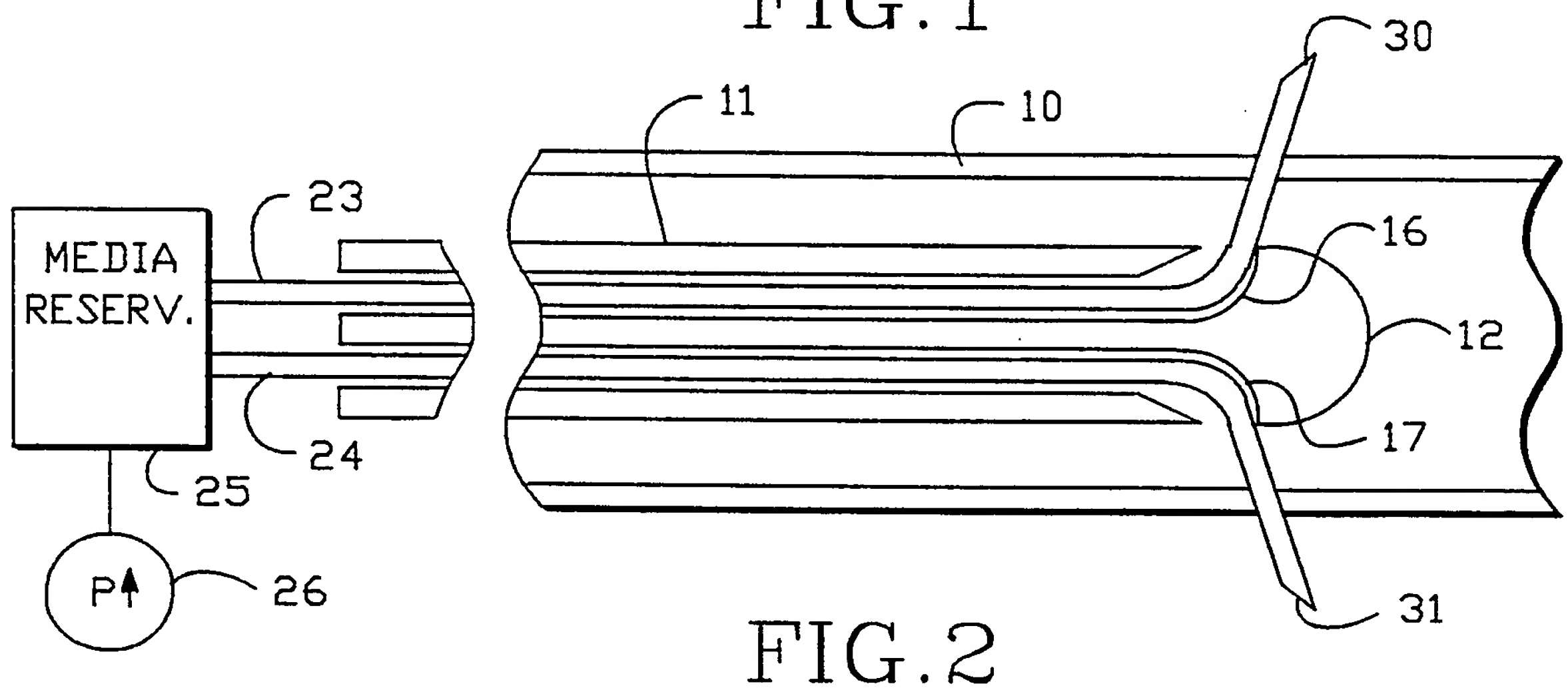
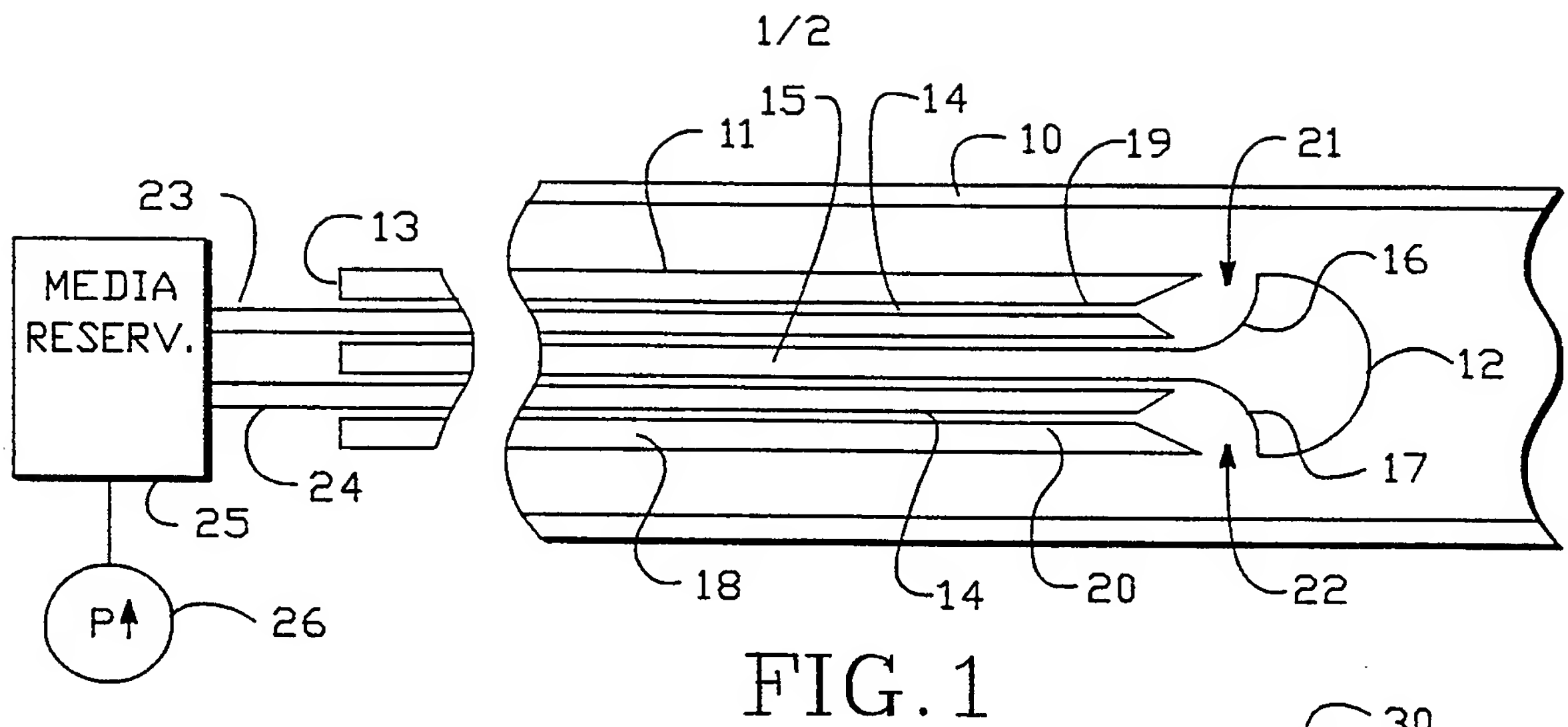
31. The apparatus of claim 30, further including:
a reservoir of material coupled to the adaptor; and
a source of pressure coupled to the reservoir to force material through
the needle.

5

32. The apparatus of claim 30, wherein the needle extends through non-
luminous mass in the extended position.

10

33. The apparatus of claim 30, further including:
a reservoir of relatively viscous material coupled to the adaptor; and
a source of pressure coupled to the reservoir to force the relatively
viscous material through the needle.



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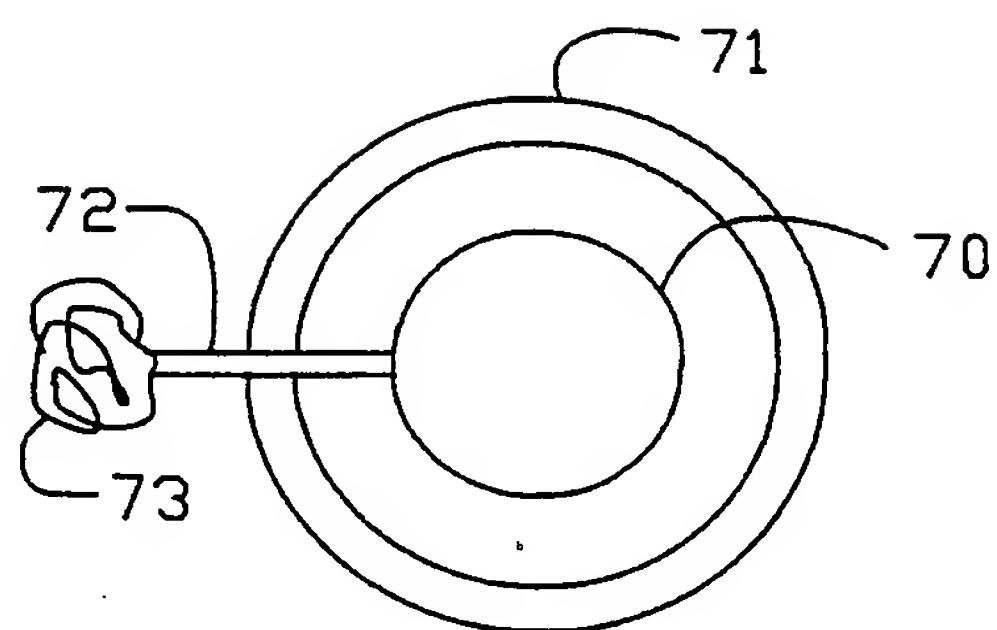


FIG. 5

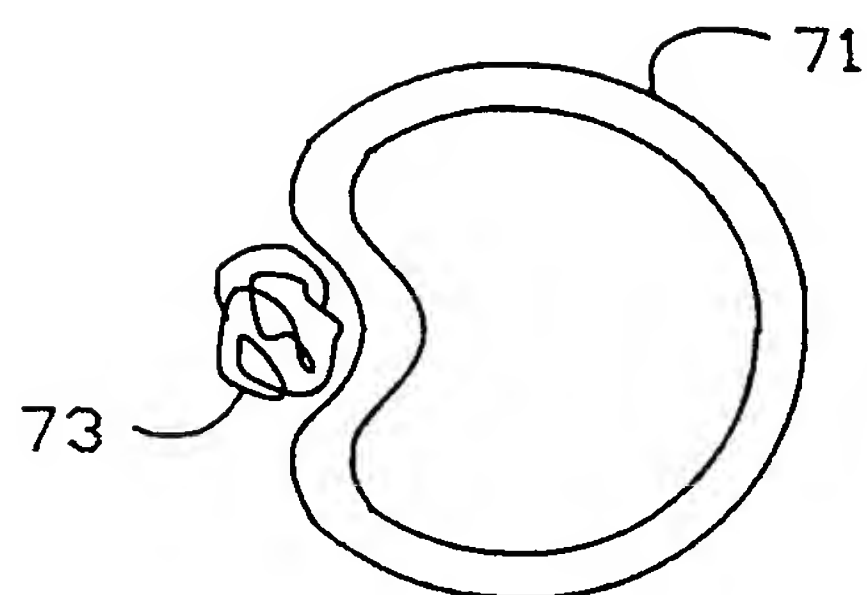


FIG. 6

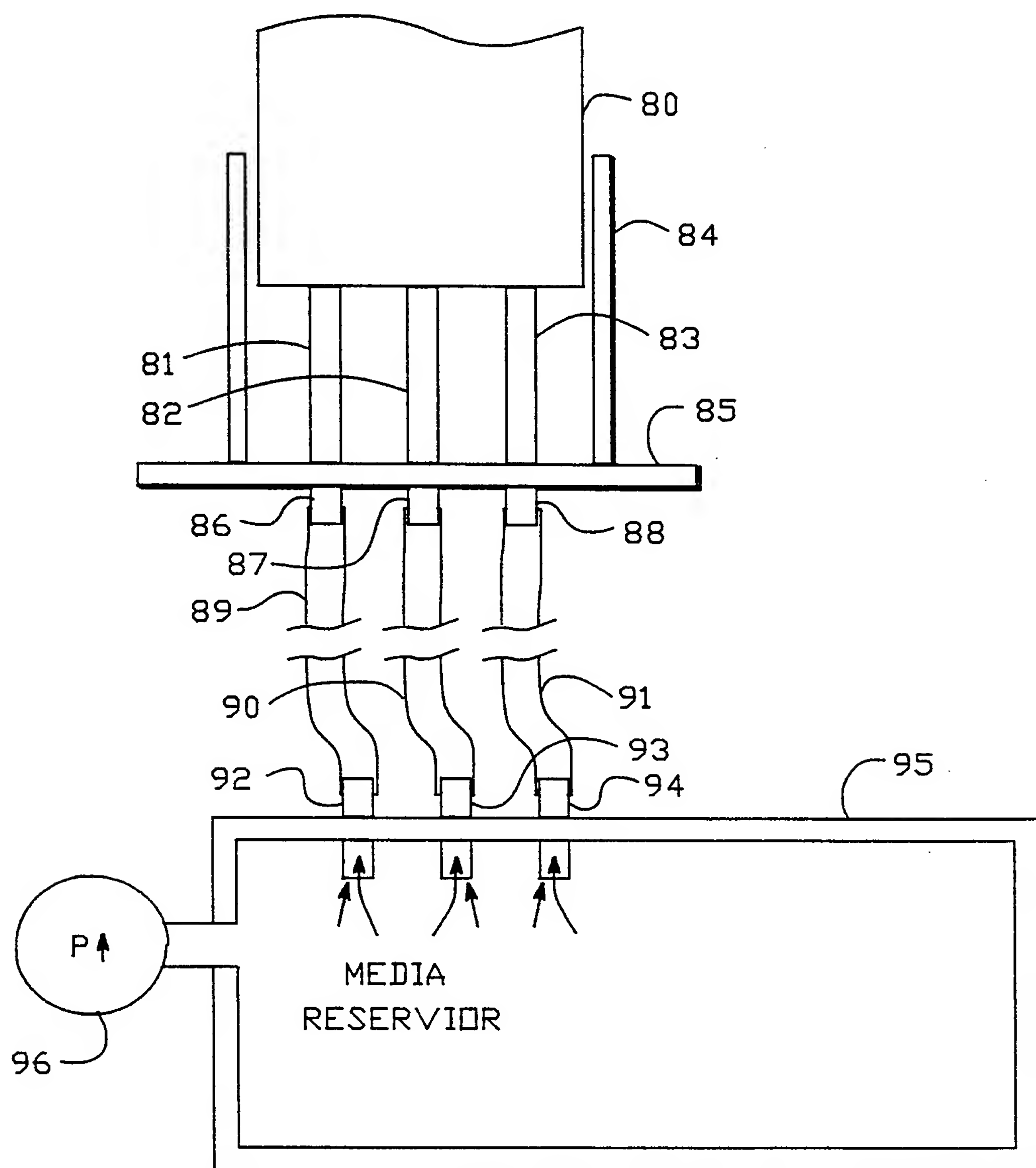


FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 96/06717

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/145 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|-----------------------|
| X | WO,A,92 10142 (PFIZER) 25 June 1992 see figures 1,4-6 --- | 1-33 |
| X | TW,A,236 572 (BAVARIA MEDIZIN-TECHNOLOGIE) 21 December 1994 see figure 3 --- | 1-33 |
| P,X | & US,A,5 419 777 (BAVARIA MEDIZIN-TECHNOLOGIE) see abstract; figures 3,5 --- | 1-33 |
| X | US,A,5 354 279 (BAVARIA MEDIZIN-TECHNOLOGIE) 11 October 1994 see abstract; figure 5 --- | 1-33 |
| X A | US,A,4 578 061 (LEMELSON) 25 March 1986 see column 2, line 66; figures 1,6 --- -/-- | 1 4 |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

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Date of the actual completion of the international search

28 August 1996

Date of mailing of the international search report

02.09.96

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+ 31-70) 340-3016

Authorized officer

Barton, S

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